UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, *et al.*, *ex rel*. ADAM HART, Plaintiff-Relator, v. MCKESSON CORP., *et al*., Defendants.	No. 15-Civ-0903 (RA) (JLC) **REDACTED**

RELATOR'S OPPOSITION TO DEFENDANTS' MOTION TO DISMISS THE SECOND AMENDED COMPLAINT

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Relator Adam Hart ("Relator") respectfully submits this opposition to Defendants McKesson Corporation's, McKesson Specialty Distribution LLC's, and McKesson Specialty Care Distribution Corporation's (collectively "McKesson") motion to dismiss the Second Amended Complaint, ECF No. 159 ("SAC" or "Complaint").

McKesson "knowingly and willfully" engaged in a nationwide scheme to provide illegal kickbacks to physician practices. As a result of annual training, its sales executives and every member of its sales force knew that the Anti-Kickback Statute ("AKS") prohibited providing anything "of value" to induce purchases, and McKesson's internal policies and procedures reinforced this training. Despite this knowledge, those same executives and salespeople formulated and executed a company-wide strategy to offer free "value-added services," the most valuable of which were the Margin Analyzer and Regimen Profiler, to induce customers to purchase drugs from McKesson. McKesson knew that these business tools had tremendous independent value: it built its sales strategy around that value; it quantified the market value of these tools to a typical large practice at $150,000; it trained and encouraged its sales force to use the value of these tools to induce customers to purchase drugs from McKesson; and it touted its success in doing so. In short, McKesson knew that the AKS prohibited it from providing anything of value for free to induce purchases, but nonetheless executed a sales strategy that it knew would directly violate that prohibition.

These allegations are more than sufficient to carry Relator's burden at the pleading stage. Once proven they are sufficient to sustain a criminal conviction under the AKS, so they necessarily give rise to a plausible inference of willfulness under the notice pleading standard for intent and knowledge under Rule 9(b). That inference is only bolstered by allegations that Relator raised compliance concerns with his supervisor, which were summarily dismissed; that

Relator had discussed the inappropriate use of the business tools with his colleagues; that McKesson destroyed relevant documents concerning its kickback practices (including after receiving a U.S. Department of Justice ("DOJ") Civil Investigative Demand ("CID")); and that McKesson purged nearly all mention of the Margin Analyzer from its website.

The SAC further alleges McKesson's nationwide scheme with particularity. It details the motivation for McKesson's scheme and how and when McKesson's sales staff were trained to execute it on a uniform nationwide basis. It contains specific examples of use of the Margin Analyzer and Regimen Profiler as inducements in every McKesson sales region nationwide and identifies specific practices across the country that entered purchase commitments with McKesson because of these free business tools, even though McKesson could not or would not offer better drug pricing than its competitors. It identifies more than 100 practices located in 46 states that received the free business tools and identifies the false and fraudulent claims for government reimbursement submitted by those practices that were tainted by McKesson's AKS violation. McKesson cannot identify a single case that has held that similar allegations fail to satisfy Rule 9(b)'s pleading requirements.

BACKGROUND

The relevant factual background of McKesson's kickback scheme is set forth in the Court's May 5, 2022 Order, ECF No. 155, at 2-9, and in Relator's Opposition to Defendants' Motion to Dismiss the First Amended Complaint ("FAC"), ECF No. 56, at 2-6. In its May 5, 2022 Order, the Court held that the allegations in Relator's FAC demonstrate that the Margin Analyzer and Regimen Profiler constitute "remuneration" under the AKS and that they "have substantial value apart from the products offered by McKesson." ECF No. 155, at 14-20. The Court also held that Relator had pled with particularity the submission of false or fraudulent

claims. *Id.* at 31. The Court held, however, that Relator had not adequately pled scienter under the AKS, which requires allegations that "give rise to a plausible inference that McKesson knew its conduct was unlawful," and it reserved judgment on whether Relator had adequately pled a nationwide scheme. *Id.* at 28, 31-34. The Court dismissed the FAC with leave to amend to address the issues identified in its May 5, 2022 Order. *Id.* at 35.

Relator filed a SAC on June 7, 2022. ECF No. 159. The SAC preserves the allegations that the Court already determined sufficient to establish that McKesson's business tools were valuable remuneration and that McKesson's scheme resulted in the submission of false and fraudulent claims. It also adds allegations demonstrating McKesson's scienter and the existence of its nationwide scheme. The SAC alleges that every McKesson customer-facing employee and senior sales executive was required to undergo AKS annual training and had express knowledge that the AKS prohibited the provision of anything of value as an inducement. SAC ¶¶ 8, 157-59. It alleges that these same employees created and implemented a national sales strategy to use the Margin Analyzer and Regimen Profiler as free kickbacks to avoid competing on price. *Id.* ¶¶ 120-22, 134-39, 160. McKesson quantified the collective "market value" of these two tools at $150,000 and described the Margin Analyzer as "one [of], if not our most valuable, tools." *Id.* ¶¶ 112, 132, 135, 138. The SAC further details specific sales pitches made on the basis of these kickbacks (including the specific sales representative, practice, when the pitch was made, and what was said), *id.* ¶ 129(a)-(p), specific instances in which these kickbacks were successful in securing purchase commitments, *id.* ¶ 131(a)-(i), and specific practices (more than 100, in 46 states) that received these kickbacks before submitting false and fraudulent claims, *id.* ¶¶ 55-57, App'x 1 & 2. And it alleges that Relator raised AKS compliance concerns with his supervisor, but was instructed to continue his sales practices; that Relator discussed the inappropriate use of

the Margin Analyzer with several of his sales colleagues; that McKesson destroyed relevant documents even after it indisputably had a duty to preserve them; and that it purged virtually all mentions of the Margin Analyzer from its website after this case began. *Id.* ¶¶ 156-70.

McKesson has moved to dismiss the SAC on two grounds: failure to allege that McKesson acted knowingly and willfully under the AKS, and failure to allege a nationwide scheme. ECF No. 172. It has not moved to dismiss any of Relator's state law claims, several of which do not impose the "willfulness" requirement, which exists under federal law.[1]

LEGAL STANDARD

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). When evaluating a motion to dismiss, the Court must "construe the complaint liberally, accepting all factual allegations in the complaint as true, and drawing all reasonable inferences in the plaintiff's favor." *Elias v. Rolling Stone LLC*, 872 F.3d 97, 104 (2d Cir. 2017).

False Claims Act ("FCA") cases generally are subject to the heightened pleading requirements of Rule 9(b). *See United States ex rel. Chorches for Bankr. Estate of Fabula v. Am. Med. Response, Inc.*, 865 F.3d 71, 81-82 (2d Cir. 2017). Rule 9(b) requires a relator to "state with particularity the circumstances constituting fraud," but allegations of "intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b); ECF No. 155, at 11-12.

[1] *See* SAC, Counts II – XXIX. For instance, the Texas Medicaid Fraud Prevention Act (Count XXVI) requires only that a person act "knowingly" to commit an unlawful act, including a violation of the Texas Anti-Kickback Statute; there is no willfulness requirement. Tex. Hum. Res. Code §§ 36.0011(a), 36.002(13).

DISCUSSION

I. The SAC Plausibly Alleges That McKesson "Knowingly and Willfully" Violated the AKS

A. The SAC Alleges That McKesson Knew the AKS Prohibited Its Conduct But Engaged in That Conduct Anyway

The SAC plausibly alleges that McKesson "knowingly and willfully" violated the AKS. The May 5, 2022 Order holds that "to satisfy the AKS's scienter requirement, Hart must plead facts that give rise to a plausible inference that McKesson knew its conduct was unlawful, although he need not allege it acted with specific knowledge of the AKS." ECF No. 155, at 28; *see also* 42 U.S.C. § 1320a-7b(h) ("[A] person need not have actual knowledge of this section or specific intent to commit a violation of this section."). The Second Circuit has clarified that there is no requirement that the defendant act with a "'corrupt' intent," – *i.e.,* an intent to "'improperly or corruptly' skew[] the patient's decision-making." *Pfizer, Inc. v. United States Dept. of Health and Human Servs.*, 42 F.4th 67, 73 (2d Cir. 2022). All that is required is that the defendant offered remuneration "with the intent to violate a known legal duty." *Id.* at 77, 79 ("Congress added the willfulness element to the AKS to avoid punishing 'an individual whose conduct, while improper, was inadvertent.'") (quoting H.R. Rep. 96-1167, at 59 (1980)).

Second Circuit precedent confirms that the "willfulness" standard is satisfied when a defendant (1) knows that the AKS prohibits the provision of anything of value as an inducement, yet (2) engages in intentional conduct to provide things of value as inducements anyway. For instance, in *United States v. Mittal*, 36 F. App'x 20 (2d Cir. 2002), the defendant appealed his criminal conviction for violating the AKS. *Id.* at 21. That case was decided before the 2010 amendment to the AKS clarifying that there is no requirement that the defendant had "actual knowledge of this section or specific intent to commit a violation of this section," 42 U.S.C. § 1320a-7b(h), and the court noted a then-existing circuit split over whether willfulness requires

specific intent, *see Mittal*, 36 F. App'x at 21. It declined, however, to resolve that question because any error in the district court's instruction was harmless. *Id.* Specifically, the court held that evidence at trial showing that the defendant knew what the AKS required — because defendant's lawyer had explained the prohibitions set forth in the statute — and yet engaged in violative conduct anyway, established "willfulness" as a matter of law, even under the stricter (and now abrogated) specific intent standard. *Id.* at 21-22. In so holding, the court focused solely upon the defendant's knowledge of the AKS's prohibitions, and did not require, or even mention, any showing of concealment or pretextual conduct, advice that the specific conduct was unlawful, or acknowledgements of concerns about the legality of the conduct. *Id.*

This District followed suit in *United States ex rel. Bilotta v. Novartis Pharmaceuticals Co.,* 50 F. Supp. 3d 497 (S.D.N.Y. 2014), denying a motion to dismiss FCA claims based on violations of the AKS. There, the plaintiffs "alleged that Novartis and the doctors involved in the alleged kickback scheme were aware of the anti-kickback laws and nevertheless engaged in conduct violating those laws." *Id.* at 515 n.6. Specifically, Novartis had ethics policies describing the AKS's prohibitions, yet its sales representatives, at the urging of senior management, provided doctors with payment, entertainment, and meals at speaker events in exchange for writing prescriptions. *Id.* at 519. The court explained that these allegations "rais[ed] a strong inference that Novartis acted knowingly and willfully in using the speaker events to induce prescription-writing in violation of the anti-kickback laws." *Id.* It further found sufficient allegations that the doctor defendants "knowingly and willfully" violated the AKS since they "were required to certify that they were not in violation of state and federal laws, including anti-kickback laws," yet still accepted remuneration based on the number of prescriptions written. *Id.* at 520; *see also United States v. Teva Pharm. USA, Inc.*, 2019 WL

1245656, at *9 (S.D.N.Y. Feb. 27, 2019) (inference of scienter under AKS "arises from evidence showing that the company violated its own compliance policies and industry standards").

Numerous other circuit courts have held that knowledge of the AKS's prohibitions combined with intentional conduct that violates the statute establishes "willfulness." In *United States v. Nowlin*, 640 F. App'x 337 (5th Cir. 2016), the Fifth Circuit held that the evidence "overwhelmingly supported" a jury's finding of willfulness under the AKS where the criminal defendant "personally signed" an enrollment application agreeing to comply with "all relevant regulations," yet entered arrangements to pay commissions for referrals. *Id.* at 344. The Seventh Circuit in *United States v. Moshiri*, 858 F.3d 1077 (7th Cir. 2017) upheld an AKS conviction where the defendant had signed a Medicare enrollment form "certify[ing] that he would comply with all Medicare rules and regulations including the [AKS]," yet was paid for providing referrals. *Id.* at 1082-83. In *United States v. Goodwin*, 974 F.3d 872 (8th Cir. 2020), the Eighth Circuit affirmed a conviction for violating the AKS, holding that the evidence was sufficient to establish a knowing and willful violation where the defendant certified that he would comply with the AKS and had "significant experience working with federal health care programs, which made it more likely he knew of the kickback prohibition" yet still received payments for referrals. *Id.* at 875-76. District courts throughout the country are in accord.[2]

[2] *See*, *e.g.*, *United States v. Teva Pharm. USA, Inc.*, 560 F. Supp. 3d 412, 421-22 (D. Mass. 2021) (willfulness was adequately alleged where "Teva knew that federal law prohibited the indirect payment of Medicare patients' copays using foundations as pass-through vehicles," because an employee had circulated a law firm presentation warning of the risks associated with donations to copay assistance charities, "but that it nonetheless engaged in such conduct"); *United States ex rel. Silva v. VICI Mktg., LLC*, 361 F. Supp. 3d 1245, 1254 (M.D. Fla. 2019) ("[T]he United States' allegations regarding Smith's scienter — that he knowingly entered the kickback schemes and knew kickbacks are illegal — are sufficient at this stage. The United States has clearly alleged that Smith knew that paying commissions per prescription to marketers regarding government-funded claims was illegal because of his research into anti-kickback statutes and his experience in the healthcare industry"); *United States ex rel. Strunck v.*

This rule is common sense and is consistent with familiar legal principles.[3] If a defendant knows that the law prohibits providing something of value as an inducement, but does so anyway, a plausible inference may be drawn that the defendant acted with an intent to violate that known legal duty. It is also consistent with the general pleading standard for alleging intent under Rule 9(b). In interpreting "willfulness" in a similar context, this District has cautioned that "courts should be wary of establishing an unreasonably high bar to surviving a motion to dismiss, lest the [] willfulness tier be all but eliminated. If plaintiffs were required to demonstrate in their pleadings that a defendant actually knew of its own violative behavior, only the rare handful of cases would be able to establish, at the motion to dismiss stage, that a defendant was actually informed of their violation of the statute." *Fullwood v. Wolfgang's Steakhouse, Inc.*, 2014 WL 6076733, at *5-7 (S.D.N.Y. Nov. 14, 2014) (interpreting "willfulness" in the Fair and Accurate Credit Transactions Act).

Here, the SAC adds allegations that every McKesson customer-facing employee received

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Mallinckrodt Ard LLC, 2020 WL 362717, at *4 (E.D. Pa. Jan. 22, 2020) (concluding that AKS scienter requirement was adequately alleged where defendant's "training programs and policies reflected an understanding of the AKS"); *United States ex rel. Bingham v. Baycare Health Sys.*, 2015 WL 4878456, at *6 (M.D. Fla. Aug. 14, 2015) (denying motion to dismiss where relator alleged that defendant "certified compliance with the [AKS] by signing 'provider applications and cost reports'" but nonetheless "paid remuneration for the purpose of inducing or rewarding referrals") (citation omitted); *United States ex rel. Pasqua v. Kan-Di-Ki LLC*, 2012 WL 12895229, at *5 (C.D. Cal. June 18, 2012) (holding that general allegations that "Defendant knew that federal and state law prohibited their giving or receiving . . . kickbacks," combined with public reports by Department of Health and Human Services "regarding the illegality of swapping schemes" that defendant allegedly engaged in were sufficient to establish willfulness under Rule 9(b)); *United States v. Genesis Glob. Healthcare*, 2021 WL 4268279, at *12 (S.D. Ga. Sept. 20, 2021) (holding that scienter under the AKS was adequately alleged where defendants were informed about "the AKS's prohibition against payments for referrals" yet "engaged in a kickback scheme to generate patient referrals").

[3] *Cf.* Restatement (Second) of Torts § 8A, cmt. b ("If the actor knows that the consequences are certain, or substantially certain, to result from his act, and still goes ahead, he is treated by the law as if he had in fact desired to produce the result.").

"extensive, annual training relating to fraud, waste, and abuse, including training specific to the AKS and Sunshine Reporting Act, which requires participants in U.S. federal health care programs to track and report payments and items of value given to physician practices. McKesson's trainings emphasized that it was a violation of the AKS to provide anything of value — no matter what the item or service was — to induce a physician practice to make purchases from McKesson." SAC ¶ 157. All participants "were required to answer questions to confirm they understood the materials they were being taught and the requirements of the AKS." *Id.* ¶ 158. Thus, at a minimum, "every Business Development Executive, every Account Executive, every Clinical Specialist, McKesson's National Vice Presidents of Sales and Account Management[,] . . . its Regional Vice Presidents of Sales and Account Management[,] . . . as well as each McKesson executive who underwent McKesson's mandatory fraud, waste, and abuse training" had full knowledge of the AKS's requirements and prohibitions. *Id.*

These same executives and employees nonetheless intentionally provided business tools and consulting services that they knew had substantial and independent value to physician practices for free, and as an express *quid pro quo* for long-term purchase commitments. The SAC alleges that McKesson's nationwide corporate strategy was to compete for business on the basis of these free and valuable kickbacks, rather than on the price of the drugs it sold. *Id.* ¶¶ 120-121, 129. McKesson trained its sales staff nationwide to sell on the basis of these free business tools. *Id.* ¶¶ 124-26. Its internal and sales materials described the Margin Analyzer and Regimen Profiler as "value-added services," and McKesson internally touted the effectiveness of these business tools at winning business, even when McKesson "could not or would not beat its competitors' pricing." *id.* ¶¶ 129-34. McKesson and its consultant even calculated the "Market Value" of these two tools at $150,000. *Id.* ¶¶ 135, 138. That "Market Value" was based on the

"costs that a physician practice would have to incur in trying to develop a similar tool for itself" by paying employees or consultants, *id.* ¶ 135; when calculated based on how much the tools and services would increase a physician practice's profits, their value was even greater. For instance, McKesson told one practice that "we can actually quantify and measure" the amount by which the tools would "increase [the practice's] profit," and ultimately estimated that "the Regimen Profiler would be worth $138,000 per year for the practice and that the Margin Analyzer would be worth $102,000 per year." *Id.* ¶ 139 (quotation marks omitted); *see also id.* ¶ 129(g). The SAC describes more than a dozen similar examples from across the country; in every single instance, the comments describing or quantifying the tools' value were made by individuals who had received AKS training on *at least* an annual basis. *Id.* ¶¶ 129, 158.

McKesson further knew that the value of these business tools was entirely independent from the core services it offered — selling prescription drugs to physician practices.[4] Practices that did not commit to purchasing the substantial majority of their drugs from McKesson did not receive these free business tools, yet could, and did, still purchase drugs from McKesson. SAC ¶ 162. Practices could also purchase the same drugs from McKesson's competitors that did not offer these business tools. And practices tried to purchase the Margin Analyzer and Regimen Profiler from McKesson even after they stopped purchasing drugs from McKesson. *Id.* ¶ 76. McKesson itself described the tools as "value-added" services — their value was added to and independent of the value of drugs McKesson sold.[5]

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[4] As detailed in Relator's Opposition to Defendants' Motion to Dismiss the First Amended Complaint, the AKS does not impose a "substantial and independent value" requirement. ECF No. 56, at 9-15. Relator incorporates that portion of the initial motion to dismiss by reference.

[5] McKesson cannot argue that it did not willfully violate the law based on its subjective interpretations of OIG advisory opinions. As an initial matter, federal regulations prohibit McKesson from offering OIG advisory opinions as a defense to AKS allegations. 42 C.F.R.

Under these circumstances, where McKesson knew that the AKS prohibited offering anything of value as an inducement, knew that its business tools were worth $150,000 per year, and yet provided those business tools for free to induce purchase commitments, it would be "plausible to infer — indeed, implausible not to infer — that [McKesson] became aware of [the AKS] violation[s]." *Fullwood*, 2014 WL 6076733, at *7; *see also supra* p. 8.

B. The SAC Contains Additional Allegations Supporting an Inference of Scienter

McKesson fails to address any of the overwhelming case law setting out the above standard. Instead, its motion focuses narrowly on whether what the SAC labels "*additional*" allegations of scienter, SAC ¶¶ 164-70, are sufficient, standing alone, to plausibly allege scienter. As a threshold matter, none of these *additional* scienter allegations are necessary for Relator to adequately allege "willfulness." There were no allegations or evidence of concealment, attorney warnings, cancellation of programs resulting from concerns about illegality, or pretextual exchanges of services in *Mittal*, *Bilotta*, *Nowlin, Moshiri, Goodwin, Teva, Silva, Bingham, Pasqua,* or *Genesis Global Healthcare.* Instead, the Second, Fifth, Seventh, and Eight Circuits, as well as numerous other district courts, held that knowledge of what the AKS prohibits coupled with intentional conduct violating those prohibitions is sufficient to satisfy the AKS's

¶ 1008.55(b) ("An advisory opinion may not be introduced into evidence by a person or entity that was not the requestor of the advisory opinion to prove that the person or entity did not violate . . . any . . . law"). In any event, as explained in Relator's opposition to McKesson's prior motion to dismiss, the OIG guidance prohibits the provision of anything of value as an inducement, particularly where it has the potential to interfere with clinical decision making, increases the cost of federal health care programs, and where the offers of remuneration are selective and relate directly or indirectly to the volume or value of business generated. ECF No. 56, at 13-14 (citing 2003 OIG Compliance Program Guidance for Pharmaceutical Manufactures, 68 Fed. Reg. 23,734, 23,736 (May 5, 2003)). Finally, factual issues involving McKesson's state of mind concerning any OIG advisory opinion are "properly addressed after full development of the factual record." *Mallinckrodt*, 2020 WL 362717, at *6 (rejecting argument that regulatory guidance was ambiguous and therefore negates allegations of scienter under the AKS).

"willfulness" requirement. Other courts have made clear that additional allegations of furtiveness are corroborative of willfulness, but not necessary. For instance, the Eleventh Circuit has held that "furtive activity is [not] required to establish willfulness under the Anti-Kickback statute. Such a requirement would be contrary to the clear statutory language, which criminalizes the paying of 'any remuneration . . . overtly or covertly.'" *United States v. Vernon*, 723 F.3d 1234 (11th Cir. 2013) (quoting 42 U.S.C. § 1320a-7b(b)(2)). Nonetheless, even taking the SAC's *additional* allegations of scienter standing alone, the SAC *does* allege McKesson's furtive conduct, which further supports the plausible inference of scienter.

1. The SAC alleges that Relator had conversations with other McKesson employees in which those employees knew that McKesson's conduct was improper but persisted anyway. Most significantly, during an AKS compliance training session:

> Relator sent an instant message to his supervisor, Bennett Holtzman (South Region Vice President of Sales and Account Management), who was also attending the same presentation, stating that McKesson's current sales practices, which included using the Margin Analyzer and the Regimen Profiler as free inducements to secure purchase commitments, violated the compliance policies that were presented in the training session. Holtzman dismissed Relator's concerns and responded by instructing Relator to continue his sales work and not to worry about the compliance policies.

SAC ¶ 164. The SAC further alleges that Relator discussed with other McKesson sales employees that McKesson's kickback scheme was "unethical and wrongful" because among other things they "encouraged physician practices to purchase the highest margin drugs . . . leading cancer patients to pay far higher co-pays and which led to far higher reimbursements from the government and private insurers." *Id.* ¶ 165. And it alleges that Relator discussed with a colleague concerns that McKesson was "inappropriately exploiting the value-added business tool . . . created originally for USON (and which USON provided to its customers for a fee) by giving the tool for free to open market customers." *Id.* ¶ 166. These allegations demonstrate that

McKesson had full knowledge, and in fact was put on notice through Relator's reporting up the supervisory chain, that its use of the Margin Analyzer and Regimen Profiler violated the AKS. *See*, *e.g., Bilotta*, 50 F. Supp. 3d at 519 (scienter established by, among other things, senior management "imposing no discipline when sale representatives were reported for non-compliance with [the company's] policies and the anti-kickback laws"). And, although Relator need not allege that McKesson acted "corruptly," these allegations make clear that McKesson knew that its conduct was not only unlawful, but also "unethical and wrongful."[6]

McKesson offers no legitimate response. It asserts (at 9) that the allegations are "unsupported by any external source," as if "external sources" are somehow required at the pleading stage. It claims (at 9) that the allegations are "self-serving," but "*[e]verything* a litigant says in support of a claim is self-serving," and labeling them as such is no ground to ignore them. *Sanders v. Melvin*, 2017 WL 4638653, at *2 (7th Cir. Oct. 17, 2017). It objects (at 10) that the allegations "lack any details about their time, place, or circumstances." But allegations of scienter may be pled generally under Rule 9(b). In any event, the SAC details Relator's confrontation with his supervisor, when it occurred, and precisely what was said.

McKesson's reliance (at 9) on *United States ex rel. Fitzer v. Allergan*, *Inc.*, 2021 WL 4133713 (D. Md. Sept. 10, 2021) is misplaced. There, the relator alleged that the defendant, who

[6] McKesson asserts (at 11) without citation that its employees' knowledge of unlawfulness cannot be attributed to McKesson. However, "[r]espondeat superior applies to violations of the False Claims Act committed by an employee of a corporation who is acting within the scope of his authority and, at least in part, for the employer's benefit." *United States v. Inc. Vill. of Island Park*, 888 F. Supp. 419, 438 (E.D.N.Y. 1995) (citing *Grand Union Co. v. United States,* 696 F.2d 888, 891 (11th Cir. 1983); *United States v. Hangar One, Inc.,* 563 F.2d 1155, 1158 (5th Cir. 1977); *United States v. O'Connell*, 890 F.2d 563, 567-68 (1st Cir. 1989)). Here, McKesson's sales employees were carrying out a corporate sales policy created by senior executives for McKesson's benefit and McKesson trained its sales representatives to execute that policy.

manufactured LAP-BAND devices, violated the AKS by including a search function on its website allowing patients to locate surgeons who could perform LAP-BAND procedures. *Id.* at *1. McKesson points to the court's conclusion that allegations that the relator (who was not an employee of defendant) reported what he claimed to be an AKS violation to defendant's representative do not alone lead to a plausible inference of "willfulness." *Id.* at *2, *7. McKesson fails to inform the Court, however, that in two subsequent decisions, the court in *Fitzer* held that an amended complaint, adding allegations that relator explained to the company representative how the conduct violated the AKS, that they "debate[d]" that claim, and that relator's assertions were met with "silence" and a statement from the representative that he would "discuss the matter with [defendant's] CEO," was sufficient to create a plausible inference of willfulness. *United States ex rel. Fitzer, v. Allergan, Inc.*, 2021 WL 5840874, at *3 (D. Md. Dec. 9, 2021) (quotation marks omitted); *see also United States ex rel. Fitzer, v. Allergan, Inc.*, 2022 WL 846211, at *4 (D. Md. Mar. 22, 2022).[7] *Fitzer* thus directly undermines rather than supports McKesson's position.

2. The SAC further alleges consciousness of guilt. McKesson and its consultant estimated the "Market Value" of the Margin Analyzer and Regimen Profiler at $125,000 and $25,000 per year, respectively. SAC ¶¶ 135, 160. As the SAC alleges (¶ 160), the actual analysis was sent to:

[7] McKesson falsely claims (at 11 n.4) that documents referenced in the SAC indicate that other companies offered similar tools. To the contrary, the very document McKesson cites states that [redacted] ECF No. 176-5, at 16 (McKesson Ex. 2). Moreover, as alleged in the SAC, McKesson stated in its sales training material that "there's nothing comparable [to the Margin Analyzer] out there. . . . I think the Margin Analyzer is truly unique and I'll often tell folks that and that we can—no one else can give you this kind of information." SAC ¶ 141; *see also* ¶ 129(c), (d), (f), (h) (sales pitches stating that only McKesson offered these tools).

> several executives, including Kirk Kaminsky, then McKesson's Senior Vice President of Open Market Sales, and Marc Owen, then President of McKesson Specialty Health. After receiving the Ernst & Young analysis, Kaminsky sent a copy to Diana Verrilli, then Vice President of Payer and Revenue Cycle Services. When he sent it, he cautioned: "You didn't get this from me … ok?"

McKesson argues (at 13) that there could be "a number of reasons why Mr. Kaminsky may have written that" email. It is black letter law, however, that "if a fact (such as an email) is susceptible to two or more competing inferences, in evaluating . . . [a motion to dismiss], the Court must draw the inference that favors the plaintiff so long as it is reasonable." *In re Aluminum Warehousing Antitrust Litig.*, 95 F. Supp. 3d 419, 436 (S.D.N.Y. 2015). "[T]he existence of other, competing inferences does not prevent the plaintiff's desired inference from qualifying as reasonable unless at least one of those competing inferences rises to the level of an obvious explanation." *N.J. Carpenters Health Fund v. Royal Bank of Scotland Grp., PLC*, 709 F.3d 109, 121 (2d Cir. 2013) (quotations marks omitted). McKesson offers *no* competing explanation, much less an "obvious" one.[8]

3. The SAC further alleges that McKesson has attempted to conceal evidence of its prior conduct. After receiving a CID from the DOJ in August 2015 arising from this action, McKesson requested that Relator return his McKesson computer. *Id.* ¶ 168. Despite knowledge

[8] McKesson also suggests (at 12) that the document is "irrelevant" because it relates to McKesson's USON division rather than its Open Market division. Not so. The document was in the hands of the Senior Vice President of Open Market Sales and shows that the Margin Analyzer and Regimen Profiler — the same tools that the "open market" division offered as free inducements — had a combined market value of $150,000 per year. SAC ¶¶ 50, 115, 135. Any executive who read that document and knew that McKesson gave the tools away as free inducements — such as its *Senior Vice President of Open Market Sales* – would immediately know that McKesson was doing what the AKS prohibits. McKesson's attempt (at 13 n.6) to suggest that this document shows that McKesson "removed" the Margin Analyzer from its list of priorities simply misreads the document. McKesson abandoned an attempt to *automate* the preparation of the Margin Analyzer instead of continuing to rely on manual preparation. *Cf.* SAC ¶ 5 (describing an aspect of manual preparation of the Margin Analyzer).

that the computer "contained a trove of relevant documents responsive to the CID," it promptly destroyed the entire contents of that computer. *Id.* A copy of the documents from this laptop was preserved only because Relator had made a back-up copy. *Id.* McKesson also failed to maintain or preserve any records of its employees' AKS compliance training, and has further destroyed a substantial portion of the documents and communications from the relevant period concerning its use of the Margin Analyzer and Regimen Profiler. *Id.* ¶¶ 169-70. The destruction of relevant documents — including destruction after McKesson had a duty to preserve those documents — supports the plausible inference of scienter.[9]

McKesson has no answer for these allegations and the inferences they support. It incorrectly claims (at 14) that "[o]n a full record, Judge Cott found that there was nothing to suggest that McKesson improperly destroyed documents." Relator first raised this issue to Judge Cott in connection with a request to conduct limited discovery into McKesson's document retention and production efforts. ECF No. 138. Judge Cott declined the request "without prejudice," explaining that Relator was seeking "discovery on discovery," which he believed was not appropriate at that stage in the litigation, before the motion to dismiss was decided.[10] That decision "without prejudice" says nothing about the sufficiency of the allegations in the SAC. It

[9] *See*, *e.g. Burciaga v. GEO Grp., Inc.*, 2017 WL 10605270, at *8 (S.D. Cal. Feb. 28, 2017) (proof of destruction of records creates a genuine dispute of material fact on defendant's scienter in an FCA case); *S.E.C. v. Suterwalla*, 2008 WL 9371764, at *4 (S.D. Cal. Feb. 4, 2008) (erasing files concerning trades after being served with preliminary injunction forbidding document destruction supports scienter in insider trading case).

[10] 1/12/2022 Hr'g Tr. 8:17-23 ("I am leery about allowing discovery on discovery to proceed at this moment in time. Again, as we have said many times in the last year, a lot of my rulings are subject to how the case continues to unfold, and obviously that will depend in large part on Judge Abram's [sic] decision on the motion to dismiss, which is pending."); 21:17-22:20 (explaining that the Court's ruling was "without prejudice to being renewed down the road if the record develops in such a way that it would be appropriate"). Nor was the decision on "a full record"; there was no testimony, and no discovery was taken about McKesson's document destruction practices.

certainly does not support McKesson's undeveloped request (at 14) to strike the document destruction allegations.[11]

Finally, the SAC alleges that after the start of this case, McKesson stripped its website of references to the Margin Analyzer and removed a customer testimonial video touting its value, which gives rise to plausible inference of McKesson's knowledge of its wrongdoing. SAC ¶ 167. Its only response is to suggest once again (at 15) that it *may* have had some innocent reasons for doing so. But again, it fails to even state those supposed reasons, much less establish that they were so "obvious" as to eliminate any plausible inference of scienter. *See supra* pp. 15-16.

II. Relator Has Adequately Alleged a Nationwide Fraudulent Scheme

The SAC alleges with particularity that McKesson engaged in a top-down nationwide strategy to offer its business tools for free to induce customers to purchase drugs from McKesson, which allowed McKesson to avoid competition on the basis of price. SAC ¶ 120. It explains how McKesson designed a uniform nationwide sales strategy centered on the Margin Analyzer and Regimen Profiler, identifying training materials and nationwide meetings that instructed salespeople to emphasize the value of the business tools and sell primarily on their

[11] "To prevail on a Rule 12(f) motion to strike, a party must demonstrate that (1) no evidence in support of the allegations would be admissible; (2) that the allegations have no bearing on the issues in the case; and (3) that to permit the allegations to stand would result in prejudice to the movant." *Landesbank Baden-Württemberg v. RBS Holdings USA Inc.*, 14 F. Supp. 3d 488, 497 (S.D.N.Y. 2014) (quotation marks and alterations omitted). McKesson has not even attempted to make such a showing. Evidence supporting McKesson's destruction of relevant documents is directly relevant to McKesson's scienter and would certainly be admissible. McKesson's bald assertion that the allegations (at 14) are "outrageous and unsupported" ignores the fact that McKesson has already *admitted* the bulk of them. ECF No. 141, at 2 & n.2 (admitting that McKesson received Relator's laptop in September 2015, wiped the laptop at that time, and failed to preserve any of its contents, despite those events "post-dat[ing] service of the CID").

value. *Id.* ¶¶ 123-27. It alleges that at national sales meetings and on quarterly conference calls "attended by all BDEs, Regional Vice Presidents, the National Sales Vice President, the President of the 'open market division,' and other senior McKesson executives," attendees "routinely discussed" how these business tools were "critical sales tools" that resulted in major purchasing commitments. *Id.* ¶ 127. It also demonstrates how McKesson's sales staff faithfully followed those top-down instructions on a nationwide basis, describing, and incorporating by reference, scores of specific McKesson presentations, emails, tool kits, and communications with customers nationwide implementing this nationwide strategy. *Id.* ¶¶ 120-22, 130. It shows how McKesson's salespeople used the Margin Analyzer and Regimen Profiler as inducements pursuant to this strategy in each of McKesson's four then-existing sales regions, belying McKesson's assertion that its alleged misconduct might have been localized in Relator's region. *Id.* ¶ 129 (detailing sales pitches, including who made them, when, to whom, and what was said).

The SAC further details how McKesson's uniform nationwide strategies were used with specific physician practices throughout the country. It describes McKesson correspondence discussing examples of particular practices from across the country that committed to purchase drugs from McKesson because of the value they received from the Margin Analyzer and Regimen Profiler, even though McKesson could not offer better drug prices than its competitors. *Id.* ¶ 131. It identifies 113 practices located in 34 states that received the Margin Analyzer for free, 299 practices located in 42 states that received the Regimen Profiler for free, and when they received them, thus demonstrating the nationwide reach of McKesson's kickback scheme. *Id.* ¶¶ 56, 113, App'x 1 & 2. Each Margin Analyzer created by McKesson and sent to these physician practices "set out the specific claims for Medicare reimbursement that the physician practice made in the prior quarter." *Id.* ¶ 57. The SAC identifies and incorporates those Margin

Analyzers (including their embedded lists of Medicare claims); accordingly, it identifies false and fraudulent claims that were submitted by practices nationwide. *Id.*

McKesson asserts that Relator's allegations (at 19) are "vague and conclusory," but it would be difficult to imagine more detailed or complete allegations of nationwide conduct. Courts have found similar (as well as substantially less particularized) allegations more than sufficient under Rule 9(b). *See*, *e.g., Bilotta*, 50 F. Supp. 3d at 516; *United States ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 30, 31 (1st Cir. 2009) (The Relator "alleged facts that false claims were in fact filed by the [eight] medical providers he identified, which further supports a strong inference that such claims were also filed nationwide.").

McKesson's motion (at 19-22) ignores the vast majority of these allegations, focusing myopically on a small fraction of the SAC allegations, and asks the Court to consider them in isolation. *See Yoder v. Orthomolecular Nutrition Inst., Inc.*, 751 F.2d 555, 562 (2d Cir. 1985) ("It is elementary that, on a motion to dismiss, a complaint must be read as a whole, drawing all inferences favorable to the pleader."). For instance, the document cited in SAC ¶ 121(a), ECF No. 176-8 (McKesson Ex. 5), describes [redacted] McKesson claims (at 20) that this document does not support Relator's allegations of a nationwide scheme because it does not say on its face "whether McKesson actually adopted the approach discussed." That ignores the other portions of the SAC, which allege with particularity that McKesson did exactly what this presentation had directed. *See*, *e.g.*, SAC ¶¶ 123-27, 129. Allegations in a complaint must be viewed collectively, not in isolation. *See Yoder*, 751 F.2d at 562.

McKesson's assertion (at 21) that the Complaint only contains allegations of "value-added" services and not "specific allegations regarding the MA or RP" ignores the SAC's allegations that the Margin Analyzer and Regimen Profiler *are* these value-added services. *E.g.* SAC ¶ 117 ("In countless instances, [McKesson] has referred to the Margin Analyzer and Regimen Profiler as 'value-added services' that McKesson offers."); *id.* ¶ 134; *see also id.* ¶¶ 121(c), 122, 126, 129(f), 131(c), 131(i), 140-41, 160.[12] Similarly, McKesson asserts (at 22) that the two appendices listing hundreds of practices nationwide that received McKesson's inducements "leave[] wholly unclear how the MA or RP were allegedly used by McKesson as a kickback." This ignores that the remainder of the SAC alleges precisely how McKesson used the Margin Analyzer and Regimen Profilers as kickbacks to avoid competing on price.[13]

[12] McKesson's attacks on the documents cited in the SAC ¶ 121(b) and (c) suffer from the same error. McKesson says (at 20) that the email described in paragraph 121(b) does not mention the Margin Analyzer or Regimen Profiler, only "value-add[ed] services" that McKesson used to compete without lowering its drug prices. ECF No. 176-9 (McKesson Ex. 6). Again, this ignores the SAC's allegations that the Margin Analyzer and Regimen Profiler were McKesson's most valuable "value-added services." McKesson similarly argues (at 20) that the RFP Response Toolkit cited in paragraph 121(c) describes a suite of "McKesson products, programs, and services," but it ignores that the document specifically describes the Margin Analyzer and Regimen Profiler in detail, and that outside of these documents, McKesson instructed its salespeople to sell on the basis of these free kickbacks. SAC ¶¶ 121(c), 124-29.

[13] The cases McKesson cites (at 22) are inapposite. In *Suarez v. AbbVie, Inc.*, 503 F. Supp. 3d 711 (N.D. Ill. 2020), the court held that relator did not adequately plead a nationwide scheme where there were "no allegations that a doctor in another state prescribed Humira because of" the kickback at issue and where Relator could only identify one patient that was enrolled in a federal healthcare program. *Id.* at 731-32. In *Conte v. Kingston NH Operations LLC*, 2022 WL 356753 (N.D.N.Y. Feb. 7, 2022), the court determined that plaintiff had not alleged how a nursing home submitted false or fraudulent claims by defying state-issued mask mandates and social distancing during the COVID pandemic, and furthermore that plaintiff had not adequately alleged that a single claim was submitted for government reimbursement. *Id.* at *14. In *United States ex rel. Doe v. Lincare Holdings, Inc.*, 2017 WL 752288 (S.D. Miss. Feb. 27, 2017), the complaint provided no allegations of any false claims that were submitted by the defendant. *Id.* at *6. Here, Relator has identified instructions provided to sales personnel nationwide, hundreds of physician practices throughout the country that received kickbacks, and the false and fraudulent claims submitted to federal healthcare programs tainted by those kickbacks.

McKesson ends with a brief argument (at 23) that Relator must also allege that customers who were provided the free kickbacks "actually used the tools or made purchasing decisions based on them." That is not the law. This District and numerous other courts have concluded that offering or receiving a kickback renders any subsequent claim false or fraudulent under the FCA, regardless of whether the kickback actually influenced the purchasing decision. *See*, *e.g.*, *United States ex rel. Greenfield v. Medco Health Sols., Inc.,* 880 F.3d 89, 96 (3d Cir. 2018); *United States v. Teva Pharm. USA, Inc.*, 2016 WL 750720, at *17 (S.D.N.Y. Feb. 22, 2016) (rejecting argument "that the AKS contains a 'but for' causation requirement," citing rule adopted by the "Third, Fifth, Seventh, Ninth, and Tenth Circuits: that 'the [Relator] need only prove that 'one purpose' of remuneration is to induce a person to use a service for which payment is made under a federal health care program").

Relator acknowledges that the Eighth Circuit reached a different result in *United States ex rel. Cairns v. D.S. Medical LLC*, 2022 WL 2930946, at *4 (8th Cir. July 26, 2022) in an opinion issued after McKesson filed its motion. The 2010 amendment to the FCA clarified, among other things, that a claim to the government that "includes items or services resulting from [an AKS] violation . . . constitutes a false or fraudulent claim." 42 U.S.C. 1320a-7b(g). The *Cairns* court concluded that the term "resulting from," imposes a "but-for" causation requirement, relying on the Supreme Court's decision in *Burrage v. United States*, 571 U.S. 204, 212 (2014), which interpreted that same term in the Controlled Substances Act. *See Cairns*, 2022 WL 2930946, at *5. *Cairns* was wrongly decided and contrary to the weight of authority.

The term "resulting from" is not defined in the 2010 Amendment, and depending on context, could be subject to more than one interpretation. As *Burrage* made clear, courts should not interpret "resulting from" to require but for causation where there is a "textual *or contextual*

indication to the contrary." 571 U.S. at 212 (emphasis added); *Universal Church v. Geltzer*, 463 F.3d 218, 223 (2d Cir. 2006) (courts can "look to the legislative history to determine the legislative intent where the plain statutory language is ambiguous or would lead to an absurd result").[14] Here, it is undisputed that Congress passed the 2010 amendment as part of an overall effort to "strengthen[ ] whistleblower actions based on medical care kickbacks" and to avert "legal challenges that sometimes defeat legitimate enforcement efforts." 155 Cong. Rec. S10852, S10853 (daily ed. Oct. 28, 2009) (Sen. Kaufman). *Cairns* fails to consider this critical context — its result would overrule the uniform body of law prior to the 2010 amendment holding that no such "but for" requirement exists, and thus significantly weaken rather than strengthen whistleblower actions, contrary to Congress's intent. Furthermore, as the Third Circuit has explained, imposing a "but for" requirement would lead to the incongruous result whereby "'a defendant could be convicted of criminal conduct under the [Anti–Kickback Statute] for paying kickbacks to induce medical referrals, but would be insulated from civil [False Claims Act] liability for the exact same conduct, absent additional proof that each medical decision was in fact corrupted by the kickbacks." *Greenfield*, 880 F.3d at 96 (quoting Gov't Amicus Br. at 22). Numerous courts have similarly considered and rejected the reasoning set forth in *Cairns*.[15]

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[14] In an analogous context, the D.C. Circuit held the term "caused by" in the terrorism exception to the Foreign Sovereign Immunities Act does not impose a "but for" requirement since, among other things, the legislative history reflects Congress's intent that "general support" for terrorism would be sufficient. *Kilburn v. Socialist People's Libyan Arab Jamahiriya*, 376 F.3d 1123, 1128-29 (D.C. Cir. 2004).

[15] *See, e.g., id.*; *Guilfoile v. Shields*, 913 F.3d 178, 190 (1st Cir. 2019) (a plaintiff need only plead "a sufficient causal connection between an AKS violation and a claim submitted to the federal government"); *United States ex rel. Fitzer v. Allergan, Inc.*, 2022 WL 3599139, at *9-10 (D. Md. Aug. 23, 2022); *United States ex rel. Bawduniak v. Biogen Idec, Inc.*, 2018 WL 1996829, at *5 (D. Mass. Apr. 27, 2018); *United States ex rel. Kester v. Novartis Pharm. Corp.*, 41 F. Supp.3d 323, 332 (S.D.N.Y. 2014); *United States v. Medtronic PLC*, 2022 WL 541604, at *4 (C.D. Cal. Feb. 23, 2022); *United States v. Medoc Health Servs. LLC*, 470 F. Supp. 3d 638, 654-55 (N.D. Tex. 2020).

In any event, the SAC does allege that the kickbacks were the "but for" cause of purchase commitments, and the resulting false and fraudulent claims submitted by at least nine specific practices. SAC ¶ 131(a)-(i). It further identifies by name hundreds of practices throughout the country that were offered and received the free kickbacks as part of a top-down nationwide scheme; alleges that after receiving kickbacks, the practices submitted thousands of claims for federal reimbursement; and points to compilations summarizing the individual claims for federal reimbursement tainted by kickbacks from each practice. *Id.* ¶ 57 (incorporating by reference the Margin Analyzers that included lists of all claims submitted by the respective practice in the previous calendar quarter). These "'representative samples' of fraudulent conduct" are more than sufficient to satisfy Rule 9(b). *Bilotta,* 50 F. Supp.3d at 518 (quoting *United States v. Bank of New York Mellon,* 941 F.Supp.2d 438, 481-82 (S.D.N.Y.2013)); *see also United States ex rel. Kester v. Novartis Pharm. Corp,* 23 F. Supp. 3d 242, 258 (S.D.N.Y. 2014) ("In cases where the alleged fraudulent scheme is extensive and involves 'numerous transactions that occurred over a long period of time, . . . it [is] impractical to require the plaintiff to plead the specifics with respect to each and every instance of fraudulent conduct [to comply with Rule 9(b)].'") (quoting *In re Cardiac Devices Qui Tam Litig.,* 221 F.R.D. 318, 333 (D. Conn. 2004)).

III. McKesson Incorrectly Claims that the SAC May Not Cite to Investigative Material

Faced with the mountain of particularized allegations in the SAC concerning McKesson's nationwide kickback scheme, McKesson urges the Court (at 17-19) to disregard any allegations based on material that it claims was produced in discovery. That request is baseless. As an initial matter, the material that McKesson complains of was obtained by the DOJ pursuant to a CID in connection with its investigation of McKesson's conduct. DOJ provided those materials to Relator as permitted by statute. *See* 31 U.S.C. 3733(a)(1)(D). They are "discovery material"

only in the sense that Relator produced all of this material to McKesson in response to McKesson's request for production of these very documents.

But even if considered "discovery material," this Court has ordered that such material can be used in an amended complaint, and McKesson stipulated to that order, thereby waiving the argument it makes here. ECF No. 78, § 6.1 (Stipulated Protective Order stating that a "Receiving Party may use" discovery material produced "in connection with this Action only for prosecuting, defending, or attempting to settle this Action, including any amendments to the pleadings"). Moreover, the case law is clear that parties are permitted to rely on discovery documents in amended pleadings, including in FCA cases.[16]

The only case McKesson cites (at 18) is an unreported decision from the Southern District of Florida, *United States ex rel. Bingham v. HCA, Inc.*, 2016 WL 6027115 (S.D. Fla. Oct. 14, 2016). Putting aside that *Bingham* departs from a long line of authority in this District, the concerns that motivated that decision are absent here. There, the court expressed concern that "[a]llowing a *qui tam* relator to amend his or her complaint after conducting further discovery would mean that the government will have been compelled to decide whether to not to intervene absent complete information about the relator's cause of action." *Id.* at *5. That is not an issue here, where the documents that McKesson has challenged were gathered by the government in response to a CID before the government made its intervention decision.

[16] *See*, *e.g.*, *United States ex rel. Raffington v. Bon Secours Health Sys., Inc.*, 285 F. Supp. 3d 759, 774-75 (S.D.N.Y. 2018) (holding that Relator may rely on discovery material in an amended complaint); *United States ex rel. Galmines v. Novartis Pharm. Corp.*, 88 F. Supp. 3d 447, 451 (E.D. Pa. 2015) (same); *United States ex rel. Fox Rx, Inc. v. Omnicare, Inc.*, 2013 WL 2303768, at *4 n.9 (N.D. Ga. May 17, 2013) (same); *Trustees of the N.Y.C. Dist. Council of Carpenters Pension Fund v. Lee*, 2016 WL 1064616, at *1 (S.D.N.Y. Mar. 14, 2016); *FDIC v. FSI Futures, Inc.*, 1991 WL 224302, at *5 (S.D.N.Y. Oct. 16, 1991).

Finally, McKesson makes a token assertion (at 18) that the FCA's "original source" requirement bars the citation to discovery material in an amended complaint. That ignores the term's statutory definition: "an individual who . . . has voluntarily disclosed to the Government the information on which [FCA] allegations . . . are based" prior to public disclosure of those allegations. 31 U.S.C. § 3730(e)(4)(B). Relator squarely fits that definition. In any event, there is no requirement, in the FCA's "original source" provision or elsewhere, that a relator must have personal knowledge of each and every allegation pled in an FCA complaint.[17]

IV. The SAC Adequately Alleges Continuing Violations

McKesson's final argument (at 24-25) is that the SAC does not adequately allege claims after 2015. But the SAC alleges that McKesson used its business tools as illegal kickbacks through at least 2019, and further identifies specific practices that received these business tools through at least 2017. *See* SAC ¶ 54; *id.* App'x 1. "[M]ulti-year fraud allegations need not contain detailed allegation of all facts supporting each and every instance of submission of a false claim… and can sufficiently state the circumstance of 'time' by outlining the time period over which they were executed." *United States ex rel. El-Amin v. George Washington Univ.*, 2005 WL 485971, at *9 (D.D.C. Feb. 25, 2005) (citing cases). Indeed, McKesson itself (in a different context, when it thinks this fact will help it) concedes (at 15) that it "still openly advertise[s]" the Regimen Profiler. The SAC therefore more than adequately alleges a continuing fraudulent scheme using the business tools as kickbacks.

[17] *See United States v. Organon USA, Inc.*, 2013 WL 12142351, at *27 (S.D. Tex. Feb. 1, 2013) ("The relator does not have to have knowledge about every element or detail of his complaint as long as he has knowledge of any essential detail."); *United States ex rel. Stinson, Lyons, Gerlin, & Bustamante, P.A. v. Prudential Ins. Co.*, 944 F.2d 1149, 1160 (3d Cir. 1991) (relator need not have direct knowledge of all the relevant information and can qualify as original source as long as he possesses some substantive information about the particular fraud).

Respectfully Submitted,

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